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PTO/SB/21 (09-04)

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Application Number 10/519,183

Filing Date December 21, 2004

First Named Inventor Sissy M. Jhiang

Art Unit To Be Determined

Examiner Name To Be Determined

Attorney Docket Number 22727/04288

ENCLOSURES (Check all that apply)

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| <input type="checkbox"/> Fee Transmittal Form | <input type="checkbox"/> Drawing(s) | <input type="checkbox"/> After Allowance Communication to TC |
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| <input type="checkbox"/> Reply to Missing Parts/Incomplete Application | <input type="checkbox"/> Landscape Table on CD | |
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Remarks

Return receipt postcard
Form PTO/SB/08A and 08B (eight pages)
Fifty-five documents

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name Calfee, Halter & Griswold LLP

Signature *Sean Myers-Payne*

Printed name Sean C. Myers-Payne

Date November 17, 2005

Reg. No. 42,920

CERTIFICATE OF TRANSMISSION/MAILING

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PATENT
Customer No. 24024
Attorney Docket No. 22727/04288

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Jhiang *et al.*) Group Art Unit: To Be Determined
)
Application No.: 10/519,183) Examiner: To Be Determined
)
Filed: December 21, 2004) Attorney Docket No.: 22727/04288
)
For: Modified Sodium Iodide Symporter)
Proteins and Genes for Imaging)
And Cancer Therapy)

Mail Stop Amendment
Commissioner For Patents
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INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 CFR §§ 1.56 and 1.97(b), Applicants brings to the attention of the Examiner the documents listed on the attached PTO/SB/08A and PTO/SB/08B. This Information Disclosure Statement is being filed before the receipt of a First Office Action. Under the provisions of 37 C.F.R. § 1.97(b), no fee is due.

Copies of the non-U.S. patent listed documents are attached. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute

Application No. 10/519,183
Attorney Docket No. 22727/04288
Information Disclosure Statement

“prior art” under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of the Statement, please charge the fee to our deposit account number 03-0172.

Respectfully submitted,

Date: Nov. 17, 2005



Sean C. Myers-Payne

Reg. No. 42,920

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	8
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Application Number	10/519,183
Filing Date	December 21, 2004
First Named Inventor	Sissy M. Jhiang
Art Unit	To Be Determined
Examiner's Name	To Be Determined
Attorney Docket Number	22727/04288

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

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				Application Number	10/519,183
				Filing Date	December 21, 2004
				First Named Inventor	Sissy M. Jhiang
				Art Unit	To Be Determined
				Examiner's Name	To Be Determined
Sheet	2	of	8	Attorney Docket Number	22727/04288

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		BARTH RF <i>et al.</i> "Boron neutron capture therapy of brain tumors: enhanced survival and cure following blood-brain barrier disruption and intracarotid injection of sodium borocaptate and boronophenylalanine", <u>Int. J. Radiat. Oncol. Biol. Phys.</u> 2000; 47 : 209-218.	
		BARTH RF <i>et al.</i> "Boron neutron capture therapy of brain tumors: enhanced survival following intracarotid injection of either sodium borocaptate or boronophenylalanine with or without blood-brain barrier disruption", <u>Cancer Res.</u> 1997; 57 : 1129-1136.	
		BLASBERG RG and TJUVAJEV JG. "Herpes simplex virus thymidine kinase as a marker/reporter gene for PET imaging of gene therapy", <u>Q. J. Nucl. Med.</u> 1999; 43 : 163-169.	
		BOLAND A <i>et al.</i> "Adenovirus-mediated transfer of the thyroid sodium/iodide symporter gene into tumors for a targeted radiotherapy", <u>Cancer Res.</u> 2000; 60 : 3484-3492.	
		BONETTA L "Getting Proteins Into Cells", <u>The Scientist</u> 2002, 16 : 38-40.	
		CASTRO MR <i>et al.</i> "Monoclonal antibodies against the human sodium iodide symporter: utility for immunocytochemistry of thyroid cancer", <u>J. Endocrinol.</u> 1999; 163 : 495-504.	
		CHO JY <i>et al.</i> "Expression and activity of human Na ⁺ /I ⁻ symporter in human glioma cells by adenovirus-mediated gene delivery", <u>Gene Ther.</u> 2000; 7 : 740-749.	
		CHO JY <i>et al.</i> "Hormonal regulation of radioiodide uptake activity and Na ⁺ /I ⁻ symporter expression in mammary glands", <u>J. Clin. Endocrinol. Metab.</u> 2000; 85 : 2936-2943.	
		CHO JY <i>et al.</i> "In vivo imaging and radioiodine therapy following sodium iodide symporter gene transfer in animal model of intracerebral gliomas", <u>Gene Therapy</u> 2002; 9 : 1139-1145.	

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Sheet	3	of	8	Attorney Docket Number	22727/04288

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		CLENDENON NR <i>et al.</i> "Boron neutron capture therapy of a rat glioma", <u>Neurosurgery</u> 1990; 26: 47-55.	
		COBB LM <i>et al.</i> "Relative concentration of astatine-211 and iodine-125 by human fetal thyroid and carcinoma of the thyroid in nude mice", <u>Radiother. Oncol.</u> 1989; 13: 203-209.	
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		DAI G <i>et al.</i> "Cloning and characterization of the thyroid iodide transporter", <u>Nature</u> 1996; 379: 458-460.	
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		GOODMAN JH <i>et al.</i> "Inhibition of tumor growth in a glioma model treated with boron neutron capture therapy", <u>Neurosurgery</u> 1990; 27: 383-388.	
		HABERKORN U "Gene Therapy with Sodium/Iodide Symporter in Hepatocarcinoma", <u>Exp. Clin. Endocrinol. Diabetes</u> 2001; 109: 60-62.	
		HELTEMES LM <i>et al.</i> "The rat sodium iodide symporter gene permits more effective radioisotope concentration than the human sodium iodide symporter gene in human and rodent cancer cells", <u>Cancer Gene Therapy</u> 2003; 10: 14-22.	
		HUANG M <i>et al.</i> "Ectopic expression of the thyroperoxidase gene augments radioiodide uptake and retention mediated by the sodium iodide symporter in non-small cell lung cancer", <u>Cancer Gene Ther.</u> 2001; 8: 612-618.	

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Sheet	4	of	8	Attorney Docket Number	22727/04288

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		JHIANG SM <i>et al.</i> "An immunohistochemical study of Na ⁺ /I ⁻ symporter in human thyroid tissues and salivary gland tissues", <u>Endocrinology</u> 1998; 139 : 4416-4419.	
		JHIANG SM "Editorial: A Monoclonal Antibody Recognizing the Extracellular Domain of Human Na ⁺ /I ⁻ Symporter and Its Potential Applications", <u>The Journal of Clinical Endocrinology & Metabolism</u> 2000; 85 : 2364-2365.	
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		KO L <i>et al.</i> "Characterization of cell cycle and biological parameters of transplantable glioma cell lines and clones", <u>Acta Neuropathol. (Berl)</u> 1980; 51 : 107-111.	
		KO L <i>et al.</i> "Morphological characterization of nitrosourea-induced glioma cell lines and clones", <u>Acta Neuropathol. (Berl)</u> 1980; 51 : 23-31.	
		KOBAYASHI N <i>et al.</i> "An improved rat brain-tumor model", <u>J. Neurosurg.</u> 1980; 53 : 808-815.	
		KOSUGI S <i>et al.</i> "High Prevalence of T354P Sodium/Iodide Symporter Gene Mutation in Japanese Patients with Iodide Transport Defect Who Have Heterogeneous Clinical Pictures", <u>Journal of Clinical Endocrinology and Metabolism</u> 1998; 83 : 4123-4129.	
		KOSUGI S <i>et al.</i> "Novel, Missense and Loss-of-Function Mutations in the Sodium/Iodide Symporter Gene Causing Iodide Transport Defect in Three Japanese Patients", <u>Journal of Clinical Endocrinology and Metabolism</u> 1998; 83 : 3373-3376.	
		KOTZERKE J <i>et al.</i> "Pharmacokinetics of ^{99m} Tc-pertechnetate and ¹⁸⁸ Re-perrhenate after oral administration of perchlorate: option for subsequent care after the use of liquid ¹⁸⁸ Re in a balloon catheter", <u>Nucl. Med. Commun.</u> 1998; 19 : 795-801.	

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NON PATENT LITERATURE DOCUMENTS			
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		LA PERLE KM <i>et al.</i> "Effect of Exogenous Human Sodium Iodide Symporter Expression on Growth of MATLyLu Cells", <u>Thyroid</u> 2003; 13 : 133-140.	
		LA PERLE KM <i>et al.</i> "In vivo expression and function of the sodium iodide symporter following gene transfer in the MATLyLu rat model of metastatic prostate cancer", <u>Prostate</u> 2002; 50 : 170-178.	
		LARSEN RH <i>et al.</i> "Blocking [²¹¹ At]astatide accumulation in normal tissues: preliminary evaluation of seven potential compounds", <u>Nucl. Med. Biol.</u> 1998; 25 : 351-357.	
		LEVY O <i>et al.</i> "Identification of a structural requirement for thyroid Na ⁺ /I ⁻ symporter (NIS) function from analysis of a mutation that causes human congenital hypothyroidism", <u>FEBS Lett.</u> 1998; 429 : 36-40.	
		LEVY O <i>et al.</i> "N-linked glycosylation of the thyroid Na ⁺ /I ⁻ symporter (NIS). Implications for its secondary structure model", <u>J. Biol. Chem.</u> 1998; 273 : 22657-22663.	
		LIN W-Y <i>et al.</i> "A comprehensive study on the blockage of thyroid and gastric uptakes of ¹⁸⁸ Re-perrhenate in endovascular irradiation using liquid-filled balloon to prevent restenosis", <u>Nucl. Med. Biol.</u> 2000; 27 :83-87.	
		MACLAREN DC <i>et al.</i> "PET imaging of transgene expression", <u>Biol. Psychiatry</u> 2000; 48 : 337-348.	
		MANDELL RB <i>et al.</i> "Radioisotope concentrator gene therapy using the sodium/iodide symporter gene", <u>Cancer Res.</u> 1999; 59 : 661-668.	
		MARSEE, DK <i>et al.</i> "Imaging of metastatic pulmonary tumors following NIS gene transfer using single photon emission computed tomography", <u>Cancer Gene Therapy</u> 2004; 11 , 121-127.	

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		MILLER DA and ROSMAN GJ. "Improved retroviral vectors for gene transfer and expression", <u>BioTechniques</u> 1989; 7: 980-990.	
		POHLENZ J. "Congenital Hypothyroidism Due to Iodide Transporter Defect Caused by Compound Heterozygous Mutations in the Sodium/Iodide Symporter Gene", <u>J. Clin. Invest.</u> 1998; 101: 1028-1035.	
		POSTEMA EJ <i>et al.</i> "Radioimmunotherapy of B-cell non-Hodgkin's lymphoma", <u>European J. Nucl. Med.</u> 2001; 28: 1725-1735.	
		RIEDEL C <i>et al.</i> "Journey of the iodide transporter NIS: from its molecular identification to its clinical role in cancer", <u>Trends Biochem Sci</u> 2001; 26: 490-496.	
		RILLEMA JA <i>et al.</i> "Effect of prolactin on sodium iodide symporter expression in mouse mammary gland explants", <u>Am J Physiol Endocrinol Metab</u> 2000; 279: E769-E772.	
		RYU K-Y <i>et al.</i> "Development of Reverse Transcription-Competitive Polymerase Chain Reaction Method to Quantitate the Expression Levels of Human Sodium Iodide Symporter", <u>Thyroid</u> 1999; 9: 405-409.	
		RYU K-Y <i>et al.</i> "Promoter Characterization of the Human Na ⁺ /I ⁻ Symporter", <u>Journal of Clinical Endocrinology and Metabolism</u> 1998; 83: 3247-3251.	
		SHEN DHY <i>et al.</i> "Effects of dose, intervention time, and radionuclide on sodium iodide symporter (NIS)-targeted radionuclide therapy", <u>Gene Therapy</u> 2004; 11: 161-169.	
		SHEN DHY <i>et al.</i> "Sodium Iodide Symporter in Health and Disease", <u>Thyroid</u> 2001; 11, No. 5: 415-425.	

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				First Named Inventor	Sissy M. Jhiang
				Art Unit	To Be Determined
				Examiner's Name	To Be Determined
Sheet	7	of	8	Attorney Docket Number	22727/04288

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue number(s), publisher, city and/or country where published	T ²
		SHIMURA H <i>et al.</i> "Iodide uptake and experimental ¹³¹ I therapy in transplanted undifferentiated thyroid cancer cells expressing the Na ⁺ /I ⁻ symporter gene", <u>Endocrinology</u> 1997; 138 : 4493-4496.	
		SMANIK PA <i>et al.</i> "Cloning of the human sodium iodide symporter", <u>Biochem. Biophys. Res. Commun.</u> 1996; 226 : 339-345.	
		SMANIK PA <i>et al.</i> "Expression, Exon-Intron Organization, and Chromosome Mapping of the Human Sodium Iodide Symporter", <u>Endocrinology</u> 1997; 138 : 3555-3558.	
		SPITZWEG C <i>et al.</i> "Approaches to gene therapy with sodium/iodide symporter", <u>Exp Clin Endocrinol Diabetes</u> 2001; 109 : 56-59.	
		SPITZWEG C <i>et al.</i> "In vivo sodium iodide symporter gene therapy of prostate cancer", <u>Gene Ther</u> 2001; 8 : 1524-1531.	
		SPITZWEG C <i>et al.</i> "Prostate-specific antigen (PSA) promoter-driven androgen-inducible expression of sodium iodide symporter in prostate cancer cell lines", <u>Cancer Res.</u> 1999; 59 : 2136-2141.	
		SPITZWEG C <i>et al.</i> "Treatment of prostate cancer by radioiodine therapy after tissue-specific expression of the sodium iodide symporter", <u>Cancer Res.</u> 2000; 60 : 6526-6530.	
		TONG Q <i>et al.</i> "Promoter Characterization of the Rat Na ⁺ /I ⁻ Symporter Gene", <u>Biochemical and Biophysical Research Communications</u> 1997; 239 : 34-41.	
		VAN SANDE J <i>et al.</i> "Anion selectivity by the sodium iodide symporter", <u>Endocrinology</u> 2003; 144 : 247-252.	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		WHELDON TE. "Radiation physics and genetic targeting: new directions for radiotherapy", <u>Phys. Med. Biol.</u> 2000; 45: R77-R95.	

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